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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,824	09/18/1998	JOSEF ENDL	P564-7029	8523

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EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	29

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/981,824	Endl et al.
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *9/27/01 and 12/18/01* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-3 and 5-54* is/are pending in the application.

4a) Of the above, claim(s) *6-17 and 19-54* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 5, and 18* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply, Sequence*

DETAILED ACTION

1. The request filed on 1/28/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/981,824 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's election of Group VII, Claims 1-3, 5, and 18, in Paper No. 27, filed 8/07/02, with traverse, is acknowledged. Applicant argues, "Applicants traverse the Examiner's lack of unity objection to the claims over U.S. 5,475,086 (Tobin) for the reason that Tobin is silent with respect to the partial peptide sequences disclosed in the subject application. Furthermore, there exists among all of the claims a common inventive concept. This common inventive concept is that for all of the claimed sequences, the sequences consist of the T cell epitopes commonly recognized by the human immune system." It is the Examiner's position that Applicant's recitation of the open terms "comprising" and "peptide derivatives" in Claim 1 opens the claim to encompass peptides including those of the Tobin reference. Further, it is the Examiner's position that by demonstrating that a claimed peptide was taught by the prior art, the Examiner has established that no unity of invention exists, thus, restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 6-17 and 19-54 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-3, 5, and 18 are being acted upon.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, the sequences of Figure 6 must be individually identified by SEQ ID NO: in the Brief Description of the Drawings. It is insufficient to simply disclose them as being "SEQ ID NOS:38-45" as it is impossible to tell which sequence is which.

5. In view of Applicant's Amendments and Remarks, filed 9/27/01 and 12/18/01, the previous rejections under the first and second paragraphs of 35 U.S.C. 112 have been withdrawn.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled requirements of paragraphs (1), (2), and (4) of section 3c of this title before the invention thereof by the applicant for patent.

7. Claims 1-3, 5, and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/07992 (of record), for the reasons of record as set forth in Paper No. 14, mailed 3/28/01.

Applicant's arguments, filed 9/27/01, have been fully considered but they are not persuasive. Applicant argues that "The peptide of the '992 patent has two additional N-terminal amino acid residues, i.e., V and N, that are absent from the instant claimed peptide of SEQ ID NO. 7. More importantly, SEQ ID NO. 7, contains a C-terminal isoleucine residue, which does not appear in the disclosure of the '992 patent." It is clear that the peptides encompassed by Claim 1 (in particular the elected peptide of SEQ ID NO:7) are not intended to be limited to the peptides consisting of the SEQ ID's alone. Note the use of the term "comprising" twice (line 1 and line 16) in the claim. Indeed, given the additional recitation of the undefined term "peptide derivative" (as the specification discloses only what the term "includes" at page 9, which does not indicate what the term excludes), the only clear limitation of the claim appears to be that the length of the peptide cannot exceed 25 amino acids. Therefore, it remains the Examiner's position that the peptide of WO 95/07992, VNFFRMVISNPAATHQDIDE, comprises the peptide of the instant claims.

8. Claims 1-3, 5, and 18 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,011,139 (of record), for the reasons of record as set forth in Paper No. 14, mailed 3/28/01.

Applicant's arguments, filed 9/27/01, have been fully considered but they are not persuasive. Applicant argues that "for purposes of brevity, [Applicants] respectfully request the incorporation of the comments set forth under Section V." It is the Examiner's position that given the lack of a specific definition of a "peptide derivative", SEQ ID NO:50 of the '139 patent, which differs from the claimed peptide by the addition of 2 amino acids at the N-terminus and the deletion of an amino acid at the C-terminus, comprises a "peptide derivative" of SEQ ID NO:7, thus the rejection is proper. Further, Applicant has not sufficiently demonstrated that the peptide of the prior art would not comprise "an amino acid sequence which has an equivalent specificity... as the amino acid sequences shown in ...(g) [SEQ ID NO:7]", as Applicant's argument regarding the necessity of a C-terminal isoleucine for "biological activity" does not address the claimed limitation of "specificity".

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3, 5, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 95/07992 (of record) or U.S. Patent No. 6,011,139 (of record) each in view of U.S. Patent No. 5,750,114 (of record), for the reasons of record as set forth in Paper No. 14, mailed 3/28/01.

Applicant's arguments, filed 9/27/01, have been fully considered but they are not persuasive. Applicant argues that "Applicants traverse and respectfully request the incorporation of the comments set forth under Section V." See the Examiner's rebuttal in paragraphs 7 and 8 above.

11. The following are new grounds for rejection.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-3, 5, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) Claim 1 does not comprise a complete sentence as it does not end in a period.

B) The recitation of "peptide derivative" in Claims 1-3, 5, and 18 is vague and indefinite as the term is not defined. Note that at page 9 of the specification it is disclosed that "peptide derivative" "includes" a number of types of compositions, however, said disclosure fails to limit the term, i.e., exclude anything, thus, the metes and bounds of the claims are not clear.

C) The recitation of "an amino acid sequence which has equivalent specificity" in Claims 1 is vague and indefinite as the term is not defined. Absent a specific definition for "equivalent specificity", the metes and bounds of the claim are not clear.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-3, 5, and 18 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation of:

A) "F-F-R-M-V-I-S-N-P-A-A-T-H-Q-D-I-D-F-L-I, wherein the peptide or peptide derivative of SEQ ID NO. 7 comprises a C-terminal isoleucine residue" in Claim 1,

B) "an amino acid sequence which has an equivalent specificity and/or binding affinity to human MHC molecules," in Claim 1

Applicant's amendment, filed 9/27/01 asserts that no new matter has been introduced into the claims. After careful review of the specification, however, specific written support for the newly introduced limitations has not been found.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 8:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J. Nolan

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 27, 2002

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600

Application No.: 08/981,824

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Seqs in Fig 6 must be identified.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing". If necessary

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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